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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,411	02/12/2004	Charles Gordon	5943-00300	4318

7590 03/19/2007
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EXAMINER

SCHILLINGER, ANN M


ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/777,411	Applicant(s)  GORDON ET AL.	
	Examiner Ann Schillinger	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/7/05, 12/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “21” has been used to designate both the convex superior surface and the expansion screw. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because page 22 describes Figures 6c and 6d that have not been received with the application. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet

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submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 20, 26, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-18, 21-24, 27-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sertich (U.S. Pat. No. 5,800,550). Sertich discloses the following of claim 15: an intervertebral implant for a human spine, comprising: a cage element (30) comprising a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element is configured to engage a first vertebra of the human spine (col. 2, lines 35-37; see Figure 2), and wherein the superior surface of the cage element comprises a first opening (54 or 56); an insert (70) comprising a superior surface (74) and an inferior surface (72), wherein the insert is configured to be positioned at least partially in the cage element (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through an opening (44) in a side of

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the cage element to expand the intervertebral implant by elevating the insert and moving a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 16: the intervertebral implant of claim 15, wherein intervertebral implant is configured such that the direction of movement of the expansion member (horizontal) is substantially perpendicular to the direction of movement of the insert (vertical; see Figure 1A).

Sertich discloses the following of claim 17: the intervertebral implant of claim 15, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (see Figure 1A).

Sertich discloses the following of claim 18: the intervertebral implant of claim 15, wherein the superior surface of the insert comprises osteoconductive mesh structure (col. 4, lines 17-21).

Sertich discloses the following of claim 21: an intervertebral implant for a human spine, comprising: a cage element (30) comprising a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element is configured to engage a first vertebra of the human spine (col. 2, lines 35-37; see Figure 2), and wherein the superior surface of the cage element comprises an opening (54 or 56); an insert (70) comprising a superior surface (74) and an inferior surface (72), wherein the insert is configured to be positioned in the cage element such that the inferior surface of the insert is inside of the cage element and the superior surface of the insert is outside of the cage element (see Figure 1A); and an expansion member (98, 114,

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118) configured to be advanced through an opening (44) in a side of the cage element to elevate at least a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 22: the intervertebral implant of claim 21, wherein the intervertebral implant is configured such that the direction of movement of the expansion member (horizontal) is substantially perpendicular to the direction of movement of the insert (vertical; see Figure 1A).

Sertich discloses the following of claim 23: the intervertebral implant of claim 21, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (see Figure 1A).

Sertich discloses the following of claim 24: the intervertebral implant of claim 21, wherein the superior surface of the insert comprises osteoconductive mesh structure (col. 4, lines 17-21).

Sertich discloses the following of claim 27: an intervertebral implant for a human spine, comprising: a cage element (30) with a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element comprises a first opening (58 or 60) and the superior surface of the cage element comprises a second opening (54 or 56); a first insert (element 70 that is located at element 58 or 60) configured to be positioned in the cage element proximate the first opening; a second insert (element 70 that is located at element 54 or 56) configured to be positioned in the cage element proximate the second opening (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through a third opening (44)

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in the cage element to expand the intervertebral implant by engaging the first insert and the second insert after the intervertebral implant is positioned between a first vertebra and a second vertebra of the human spine, wherein engaging the first insert comprises moving a portion of the first insert through the first opening of the cage element such that an inferior surface of the first insert engages the first vertebra of the human spine, and wherein engaging the second insert comprises moving a portion of the second insert through the second opening of the cage element such that a superior surface of the second insert engages the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 28: the intervertebral implant of claim 27, wherein intervertebral implant is configured such that the direction of movement of the expansion member (horizontal) is substantially perpendicular to the direction of movement of the first insert and the second insert (vertical; see Figure 1A).

Sertich discloses the following of claim 29: the intervertebral implant of claim 27, wherein the expansion member is configured to be advanced between a superior surface of the first insert (72 of lower element 70) and an inferior surface of the second insert (72 of upper element 70).

Sertich discloses the limitations of claims 30 and 31 in col. 4, lines 17-21.

Sertich discloses the following of claim 33: the intervertebral implant of claim 27, wherein expanding the intervertebral implant comprises increasing a height of the intervertebral implant (col. 7, lines 34-47).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 25, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sertich in view of Larsen et al. (U.S. Pat. No. 5,782,832). Sertich discloses the invention substantially as claimed, however, Sertich does not disclose a raised portion of the inferior surface of the cage that will inhibit backout of the expansion member. Larsen et al. teaches such a projection in col. 8, lines 8-29 for the purpose of traversing movement within the interior of the implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised portion of the inferior surface of the cage in order to inhibit backout of the expansion member by traversing movement within the interior of the implant.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
March 9, 2007


ALVIN J. STEWART
PRIMARY EXAMINER